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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**Applicant:** Robert E. Reiter et al. **Examiner:** Not yet known  
**Serial No.:** 09/934,773 **Group Art Unit:** 1642  
**Filed:** August 21, 2001 **Docket No.:** 30435.54USD3  
**Title:** PSCA: PROSTATE STEM CELL ANTIGEN AND USES THEREOF

**CERTIFICATE UNDER 37 CFR 1.8:**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on October 24, 2001

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**INFORMATION DISCLOSURE STATEMENT (37 C.F.R. §1.97(b)(1))**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner. They are as follows:

- WO 98/00540 published January 8, 1998 (Exhibit 1)
- Arlen, Myron et al., "Immunotherapy of Colon Cancer Using Chimeric mAb 31.1," *Critical Review in Immunology*, 1998, 18:133-8. (Exhibit 2)
- Arthur, Jill F. et al., "A Comparison of Gene Transfer Methods in Human Dendritic Cells," *Cancer Gene Therapy*, 1997, 4:17-25. (Exhibit 3)
- Ashley, David M. et al., "Bone Marrow-generated Dendritic Cells Pulsed with Tumor Extracts or Tumor RNA Induce Antitumor Immunity against Central Nervous System Tumors," *Journal of Experimental Medicine*, 6 October 1997, 186:1177-82. (Exhibit 4)

- Bamezai, Anil and Kenneth L. Rock, "Overexpressed Ly-6A.2 Mediates Cell-Cell Adhesion by Binding a Ligand Expressed on Lymphoid Cells," *Proc Nat'l Acad Sci USA*, May 1995, 92:4294-8. (Exhibit 5)
- Brakenhoff, Ruud H. et al., "The Human E48 Antigen, Highly Homologous to the Murine Ly-6 Antigen ThB, is a GPI-anchored Molecule Apparently Involved in Keratinocyte Cell-Cell Adhesion," *Journal of Cell Biology*, June 1995, 129:1677-89. (Exhibit 6)
- Braun, Benjamin S. et al., "Identification of Target Genes for the Ewing's Sarcoma EWS/FLI Fusion Protein by Representational Difference Analysis," *Molecular and Cell Biology*, August 1995, 15:4623-30. (Exhibit 7)
- Cher, Michael L. et al., "Comparative Genomic Hybridization, Allelic Imbalance, and Fluorescence In Situ Hybridization on Chromosome 8 in Prostate Cancer," *Genes, Chromosomes & Cancer*, 1994, 11:153-62. (Exhibit 8)
- Cohen, Stanley N. et al., "Nonchromosomal Antibiotic Resistance in Bacteria: Genetic Transformation of *Escherichia coli* by R-Factor DNA," *Proc. Nat'l Acad Sci USA*, August 1972, 69:2110-4. (Exhibit 9)
- Cupp, Michael R. and Osterling, Joseph E., "Prostate-Specific Antigen, Digital Rectal Examination and Transrectal Ultrasonography: Their Roles in Diagnosing Early Prostate Cancer," *Mayo Clinic Proceedings*, March 1993, 68:297-306. (Exhibit 10)
- Deleersnijder, Willy et al., "Isolation of Markers for Chondro-osteogenic Differentiation Using cDNA Library Subtraction," *Journal of Biological Chemistry*, 9 August 1996, 271:19475-82. (Exhibit 11)

- Fields, Stanley and Ok-kyu Song, "A Novel Genetic System to Detect Protein-Protein Interactions," *Nature*, 20 July 1989, 340:245-6. (Exhibit 12)
- Fong, Lawrence et al., "Induction of Tissue-Specific Autoimmune Prostatitis with Prostatic Acid Phosphatase Immunization Implications for Immunotherapy of Prostate Cancer," *Journal of Immunology*, 1997, 159:3113-7. (Exhibit 13)
- Foon, Kenneth A. et al., "Immune Response to the Carcinoembryonic Antigen in Patients Treated with an Anti-Idiotypic Antibody Vaccine," *Journal of Clinical Investigation*, July 1995, 96:334-42. (Exhibit 14)
- Fritz, Benjamin A. and Anson W. Lowe, "Polarized GP2 Secretion in MDCK Cells Via GPI Targeting and Apical Membrane-Restricted Proteolysis," *American Journal of Physiology*, January 1996, 270:G176-83. (Exhibit 15)
- Funakoshi, Satoshi et al., "Differential In Vitro and In Vivo Antitumor Effects Mediated by Anti-CD40 and AntiCD20 Monoclonal Antibodies Against Human B-Cell Lymphomas," *Journal of Immunotherapy*, 1996, 19(2):93-101. (Exhibit 16)
- Graham, F. L. and A. J. Van Der Eb, "A New Technique for the Assay of Infectivity of Human Adenovirus 5 DNA," *Virology*, 1973, 52:456-67. (Exhibit 17)
- Liu, He et al., "Constitutive and Antibody-induced Internalization of Prostate-specific Membrane Antigen," *Cancer Research*, 15 September 1998, 58:4055-60. (Exhibit 18)
- Henderson, Robert A. et al., "Human Dendritic Cells Genetically Engineered to Express High Levels of the Human Epithelial Tumor Antigen Mucin (MUC-1)," *Cancer Research*, 15 August 1996, 56:3763-70. (Exhibit 19)

- Herlyn, Dorothee et al., "Anti-Idiotypic Cancer Vaccines: Past and Future," *Cancer Immunology Immunotherapy*, 1996, 43:65-76. (Exhibit 20)
- Hodge, James W. et al., "A Recombinant Vaccinia Virus Expressing Human Prostate-Specific Antigen (PSA): Safety and Immunogenicity in a Non-Human Primate," *International Journal of Cancer*, 1995, 63:231-7. (Exhibit 21)
- Israeli, Ron S. et al., "Molecular Cloning of a Complementary DNA Encoding a Prostate-specific Membrane Antigen," *Cancer Research*, 15 January 1993, 53:227-30. (Exhibit 22)
- Jenkins, Robert B. et al., "Detection of c-myc Oncogene Amplification and Chromosomal Anomalies in Metastatic Prostatic Carcinoma by Fluorescence *in Situ* Hybridizaion," *Cancer Research*, 1 February 1997, 57:524-31. (Exhibit 23)
- Kasprzyk, Philip G. et al., "Therapy of an Animal Model of Human Gastric Cancer Using a Combination of Anti-*erbB*-2 Monoclonal Antibodies," *Cancer Research*, 15 May 1992, 52:2771-6. (Exhibit 24)
- Katz, Ben-Zion et al., "An Association Between High Ly-6A/E Expression on Tumor Cells and a Highly Malignant Phenotype," *International Journal of Cancer*, 1994, 59:684-91. (Exhibit 25)
- Kieffer, Bruno et al., "Three-Dimensional Solution Structure of the Extracellular Region of the Complement Regulatory Protein CD59, a New Cell-Surface Protein Domain Related to Snake Venom Neurotoxins," *Biochemistry*, 1994, 33:4471-82. (Exhibit 26)

- Klein, Karen A. et al., "Progression of Metastatic Human Prostate Cancer to Androgen Independence in Immunodeficient SCID Mice," *Nature Medicine*, April 1997, 3:402-8. (Exhibit 27)
- Lalani, El-Nasir et al., "Molecular and Cellular Biology of Prostate Cancer," *Cancer and Metastasis Reviews*, 1997, 16:29-66. (Exhibit 28)
- Lee, Cheryl T. and Joseph E. Oesterling, "Cancer of the Prostate: Diagnosis and Staging," *Urologic Oncology*, 1997, W. B. Saunders Company, Philadelphia, 357-77. (Exhibit 29)
- Magi-Galluzzi, C. et al., "Mitogen-Activated Protein Kinase Phosphatase 1 is Overexpressed in Prostate Cancers and is Inversely Related to Apoptosis," *Laboratory Investigation*, January 1997, 76:37-51. (Exhibit 30)
- Mao Mao et al., "*RIG-E*, a Human Homolog of the Murine Ly-6 Family, is Induced by Retinoic Acid During the Differentiation of Acute Promyelocytic Leukemia Cell," *Proc Nat'l Acad Sci USA*, June 1996, 93:5910-4. (Exhibit 31)
- Mount, Peter F. et al., "Chimeric (Mouse/Human) Anti-Colon Cancer Antibody c30.6 Inhibits the Growth of Human Colorectal Cancer Xenografts in *scid/scid* Mice," *Cancer Research*, 1 December 1994, 54:6160-6. (Exhibit 32)
- Noda, Satoshi et al., "Protection from Anti-TCR/CD3-induced Apoptosis in Immature Thymocytes by a Signal through Thymic Shared Antigen-1/Stem Cell Antigen-2," *Journal of Experimental Medicine*, May 1996, 183:2355-60. (Exhibit 33)

- Ozaki, Shuji et al., "Immunotherapy of Multiple Myeloma with a Monoclonal Antibody Directed Against a Plasma Cell-Specific Antigen, HMI.24," *Blood*, 15 October 1997, 90:3179-3186. (Exhibit 34)
- Qian, Junqi et al., "Chromosomal Anomalies in Prostatic Intreepithelial Neoplasia and Carcinoma Detected by Fluorescence *in Situ* Hybridization," *Cancer Research*, 15 November 1995, 55:5408-14. (Exhibit 35)
- Restifo, Nicholas P., "The New Vaccines: Building Viruses That Elicit Antitumor Immunity," *Current Opinion in Immunology*, October 1996, 8:658-63. (Exhibit 36)
- Ribas, Antoni et al., "Genetic Immunization for the Melanoma Antigen MART-1/Melan-A Using Recombinant Adenovirus-transduced Murine Dendritic Cells," *Cancer Research*, 15 July 1997, 57:2865-9. (Exhibit 37)
- Rowley, Janet D. et al., "Mapping Chromosome Band 11q23 in Human Acute Leukemia with Biotinylated Probes: Identification of 11q23 Translocation Breakpoints with a Yeast Artificial Chromosome," *Proc Natl Acad Sci USA*, December 1990, 87:9358-62. (Exhibit 38)
- Shepard, H. Michael et al., "Monoclonal Antibody Therapy of Human Cancer: Taking the HER2 Proto-oncogene to the Clinic," *Journal of Clinical Immunology*, 1991, 11:117-27. (Exhibit 39)
- Southern, P. J. and P. Berg, "Transformation of Mammalian Cells to Antibiotic Resistance with a Bacterial Gene Under Control of the SV40 Early Region Promoter," *Journal of Molecular and Applied Genetics*, 1982, 1:327-41. (Exhibit 40)

- Southern, E. M., "Detection of Specific Sequences Among DNA Fragments Separated by Gel Electrophoresis," *Journal of Molecular Biology*, 1975, 98:503-17. (Exhibit 41)
- Thomas, Pamela M. and Lawrence E. Samelson, "The Glycophosphatidylinositol-anchored Thy-1 Molecule Interacts with the p60<sup>src</sup> Protein Tyrosine Kinase in T Cells," *The Journal of Biological Chemistry*, 15 June 1992, 267:12317-22. (Exhibit 42)
- Thorpe, Philip E. and Walter C. J. Ross, "The Preparation and Cytotoxic Properties of Antibody-Toxin Conjugates," *Immunological Review*, 1982, 62:119-58. (Exhibit 43)
- Towbin, Harry et al., "Electrophoretic Transfer of Proteins from Polyacrylamide Gels to Nitrocellulose Sheets: Procedure and Some Applications," *Proc Nat'l Acad Sci USA*, September 1979, 76:4350-4. (Exhibit 44)
- Tsunenari, Toshiaki et al., "New Xenograft Model of Multiple Myeloma and Efficacy of a Humanized Antibody Against Human Interleukin-6 Receptor," *Blood*, 15 September 1997, 90:2437-44. (Exhibit 45)
- Udenfriend, Sidney and Krishna Kodukula, "How Glycosyl-Phosphatidylinositol-Anchored Membrane Proteins Are Made," *Annual Review of Biochemistry*, 1995, 64:563-91. (Exhibit 46)
- Veis, Deborah J. et al., "Bcl-2-Deficient Mice Demonstrate Fulminant Lymphoid Apoptosis, Polycystic Kidneys and Hypopigmented Hair," *Cell*, 22 October 1993, 75:229-40. (Exhibit 47)

- Velders, Markwin P. et al., "Immunotherapy with Low and High Affinity Monoclonal Antibodies 17-1A and 323/A3 in a Nude Mouse Xenograft Carcinoma Model," *Cancer Research*, 1 October 1995, 55:4398-4403. (Exhibit 48)
- Wagner, U. et al., "Immunological Responses to the Tumor-Associated Antigen CA 125 in Patients with Advanced Ovarian Cancer Induced by the Murine Monoclonal Anti-Idiotypic Vaccine ACA 125," *Hybridoma*, 1997, 16:33-40. (Exhibit 49)
- Wigler, Micheal et al., "DNA-Mediated Transfer of the Adenine Phosphoribosyltransferase Locus Into Mammalian Cells," *Proc Nat'l Acad Sci USA*, March 1979, 76:1373-6. (Exhibit 50)
- Yang, Yongmin et al., "Differential Expression of Cytokeratin mRNA and Protein in Normal Prostate, Prostatic Intraepithelial Neoplasia and Invasive Carcinoma," *American Journal of Pathology*, February 1997, 150:693-704. (Exhibit 51)
- Zhong, Rui-kun et al., "Evaluation of Monoclonal Antibody-Mediated Anti-Acute Myeloid Leukemia Immunotherapy in a SCID/hu Model," *Leukemia Research*, 1996, 20:581-9. (Exhibit 52)
- Boulianne, Gabrielle L. et al., "Productions of Functional Chimeric Mouse/Human Antibody," *Nature*, December 1984, 312:643-6. (Exhibit 53)
- Fell, H. Perry et al., "Homologous Recombination in Hybridoma Cells: Heavy Chain Chimeric Antibody Produced by Gene Targeting," *Proc. Natl. Acad. Sci. USA*, November 1989, 86:8507-11. (Exhibit 54)



- Hellstrom, Ingegerd et al., "Strong Antitumor Activities of IgG3 Antibodies to a Human Melanoma-Associated Ganglioside," *Proc. Natl. Acad. Sci. USA*, March 1985, 82:1499-1502. (Exhibit 55)
- Hellstrom, Karl Erik and Ingegerd Hellstrom, "Antibody for Drug Delivery," in Robinson et al., eds, *Controlled Drug Delivery*, 2<sup>nd</sup> edition, Marcel Dekker, Inc. 1987, 623-53. (Exhibit 56)
- Neuberger, Michael S. et al., "Recombinant Antibodies Possessing Novel Effector Functions," *Nature*, December 13, 1984, 312:604-8. (Exhibit 57)
- Sahagan, Barbara G. et al., "A Genetically Engineered Murine/Human Chimeric Antibody Retains Specificity for Human Tumor-Associated Antigen," *The Journal of Immunology*, August 1, 1986, 137:1066-74. (Exhibit 58)
- Sharon, J. et al., "Expression of a V<sub>H</sub>C<sub>K</sub> Chimeric Protein in Mouse Myeloma Cells," *Nature*, May 1984, 309:364-7. (Exhibit 59)
- Shizuya, Hiroaki et al., "Cloning and Stable Maintenance of 300-Kilobase-Pair Fragments of Human DNA in *Escherichia coli* Using an F-Factor-Based Vector," *Proc. Natl. Acad. Sci. USA*, September 1992, 89:8794-7. (Exhibit 60)
- Tan, Lee K. et al., "A Human-Mouse Chimeric Immunoglobulin Gene With a Human Variable Region is Expressed in Mouse Myeloma Cells," *The Journal of Immunology*, November 1985, 135:3564-7. (Exhibit 61)

- Vitetta, Ellen S. et al., "Immunotoxin Therapy," in De Vita Jr., V.T. et al., eds, *Cancer: Principles and Practice of Oncology*, 4<sup>th</sup> edition, J.B. Lippincott Co., Philadelphia 1993, 2624-2636. (Exhibit 62)
- Algate, Paul A. et al., "Regulation of the Interleukin-3 (IL-3) Receptor by IL-3 in the Fetal Liver-Derived FL5.12 Cell Line," *Blood*, May 1994, 83(9):2459-68. (Exhibit 63)
- Arnon, Ruth et al., "Monoclonal Antibodies for Immunotargeting of Drugs in Cancer Therapy," *Monoclonal Antibodies and Cancer Therapy*, Reisfield, Ralph A. and Stewart Sell (eds.) 1985, 243-56. (Exhibit 64)
- Bacchetti, Silvia and Frank L. Graham, "Transfer of the Gene for Thymidine Kinase to Thymidine Kinase-Deficient Human Cells by Purified Herpes Simplex Viral DNA," *Proc. Natl. Acad. Sci. USA*, April 1977, 74(4):1590-4. (Exhibit 65)
- Berent, Susan L. et al., "Comparison of Oligonucleotide and Long DNA Fragments as Probes in DNA and RNA Dot, Southern, Northern, Colony and Plaque Hybridizations," *BioTechniques*, May/June 1985, 3:208-19. (Exhibit 66)
- Berkner, Kathleen L., "Development of Adenovirus Vectors for the Expression of Heterologous Genes," *BioTechniques*, July/August 1988, 6(7):616-29. (Exhibit 67)
- Bonkhoff, Helmut and Klaus Remberger, "Differentiation Pathways and Histogenetic Aspects of Normal and Abnormal Prostatic Growth: A Stem Cell Model," *The Prostate*, February 1996, 28(2):98-106. (Exhibit 68)
- Bonkhoff, Helmut et al., "The Proliferative Function of Basal Cells in the Normal and Hyperplastic Human Prostate," *The Prostate*, January 1994, 24(1):114-8. (Exhibit 69)

- Boshart, Michael et al., "A Very Strong Enhancer is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus," *Cell*, June 1985, 41(2):521-30. (Exhibit 70)
- Breviario, Ferruccio et al., "Interleukin-1-Inducible Genes in Endothelial Cells Cloning of a New Gene Related to C-Reactive Protein and Serum Amyloid P Component," *The Journal of Biological Chemistry*, November 5, 1992, 267(31):22190-7. (Exhibit 71)
- Brinster, Ralph L. et al., "Transgenic Mice Harboring SV40 T-Antigen Genes Develop Characteristic Brain Tumors," *Cell*, June 1984, 37:367-79. (Exhibit 72)
- Brinster, Ralph L. et al., "Introns Increase Transcriptional Efficiency in Transgenic Mice," *Proc. Natl. Acad. Sci. USA*, February 1988, 85:836-40. (Exhibit 73)
- Cluitmans, F.H.M. et al., "IL-4 Down-Regulates IL-2-, IL-3-, and GM-CSF-Induced Cytokine Gene Expression in Peripheral Blood Monocytes," *Annals of Hematology*, 1994, 68:293-8. (Exhibit 74)
- De Wit, Harry et al., "Differential Regulation of M-CSF and IL-6 Gene Expression in Monocytic Cells," *British Journal of Hematology*, 1994, 86:259-64. (Exhibit 75)
- DePamphilis, M.L. et al., "Microinjecting DNA into Mouse Ova to Study DNA Replication and Gene Expression and to Produce Transgenic Animals," *BioTechniques*, July/August 1988, 6(7):662-80. (Exhibit 76)
- Espinoza-Delgado, Igor et al., "Regulation of IL-2 Receptor Subunit Genes in Human Monocytes Differential Effects of IL-2 and IFN- $\gamma$ ," *The Journal of Immunology*, November 1, 1992, 149(9):2961-8. (Exhibit 77)

- Felgner, Philip L. et al., "Lipofection: A Highly Efficient, Lipid-Mediated DNA-Transfection Procedure," *Proc. Natl. Acad. Sci. USA*, November 1987, 84:7413-7. (Exhibit 78)
- Felgner, P.L. et al., "Cationic Liposome Mediated Transfection," *Proceedings of the Western Pharmacology Society*, 1989, 32:115-21. (Exhibit 79)
- Freireich, Emil J. et al., "Quantitative Comparison of Toxicity of Anticancer Agents in Mouse, Rat, Hamster, Dog, Monkey and Man," *Cancer Chemotherapy Reports*, May 1966, 50(4):219-44. (Exhibit 80)
- Gao, Xiang et al., "Diagnostic and Prognostic Markers for Human Prostate Cancer," *The Prostate*, April 1, 1997, 31:264-81. (Exhibit 81)
- Garabedian, Emily M. et al., "A Transgenic Mouse Model of Metastatic Prostate Cancer Originating From Neuroendocrine Cells (Prostatic Intraepithelial Neoplasia)," *Proc. Natl. Acad. Sci. USA*, December 1998, 95:15382-7. (Exhibit 82)
- Geller, Alfred I. et al., "An Efficient Deletion Mutant Packaging System for Defective Herpes Simplex Virus Vectors: Potential Applications to Human Gene Therapy and Neuronal Physiology," *Proc. Natl. Acad. Sci. USA*, November 1990, 87:8950-4. (Exhibit 83)
- Ghosh-Choudhury, Coutam et al., "Human Adenovirus Cloning Vectors Based on Infectious Bacterial Plasmids (Recombinant DNA; Ad5 Insertion Mutants; Shuttle Vectors; Gene Transfer; DNA Transfection; Bacteriophage  $\lambda$  *cos* Site; Neomycin Resistance," *Gene*, 1986, 50(1-3):161-71. (Exhibit 84)
- Greenberg, N. M. et al., "Prostate Cancer in a Transgenic Mouse," *Proc. Natl. Acad. Sci. USA*, April 1995, 92:3439-43. (Exhibit 85)

- Hock, Randy A. and A. Dusty Miller, "Retrovirus-Mediated Transfer and Expression of Drug Resistance Genes in Human Haematopoietic Progenitor Cells," *Nature*, March 1986, 320:275-7. (Exhibit 86)
- Horisberger, Michel A. et al., "Cloning and Sequence Analyses of cDNAs for Interferon- and Virus- Induced Human Mx Proteins Reveal that They Contain Putative Guanine Nucleotide-Binding Sites: Functional Study of the Corresponding Gene Promoter," *Journal of Virology*, March 1990, 64(3):1171-81. (Exhibit 87)
- Jenkins, Robert B. et al., "Detection of c-myc Oncogene Amplification and Chromosomal Anomalies in Metastatic Prostatic Carcinoma by Fluorescence *in Situ* Hybridization," *Cancer Research*, February 1, 1997, 57:524-31. (Exhibit 88)
- Kaufman, Randal J., "Identification of the Components Necessary for Adenovirus Translational Control and Their Utilization in cDNA Expression Vectors," *Proc. Natl. Acad. Sci. USA*, February 1985, 82:689-93. (Exhibit 89)
- Kaufman, Randal J., "Vectors Used for Expression in Mammalian Cells," *Methods in Enzymology*, Gene Expression Technology, David V. Goeddel, ed., 1990, 185:487-511. (Exhibit 90)
- Kay, A. B. et al., "Messenger RNA Expression of the Cytokine Gene Cluster, Interleukin 3 (IL-3), IL-4, IL-5 and Granulocyte/Macrophage Colony-stimulating Factor, In Allergen-Induced Late-Phase Cutaneous Reactions in Atopic Subjects," *Journal of Experimental Medicine*, March 1991, 173:775-8. (Exhibit 91)

- Lagoo, Anand S. et al., "IL-2, IL-4 and IFN- $\gamma$  Gene Expression Versus Secretion in Superantigen-Activated T Cells," *The Journal of Immunology*, February 15, 1994, 152(4):1641-52. (Exhibit 92)
- Li, Yi-Ping and Philip Stashenko, "Proinflammatory Cytokines Tumor Necrosis Factor- $\alpha$  and IL-6, But Not IL-1, Down-Regulate the Osteocalcin Gene Promoter," *The Journal of Immunology*, February 1, 1992, 148(3):788-94. (Exhibit 93)
- Martinez, Olivia M. et al., "IL-2 and IL-5 Gene Expression in Response to Alloantigen in Liver Allograft Recipients and In Vitro," *Transplantation*, May 1993, 55(5):1159-66. (Exhibit 94)
- Mauviel, Alain et al., "Leukoregulin, A T Cell-Derived Cytokine, Induces IL-8 Gene Expression and Secretion in Human Skin Fibroblasts Demonstration of Enhanced NF- $\lambda$ B-Driven Promoter Activity," *The Journal of Immunology*, November 1, 1992, 149(9):2969-76. (Exhibit 95)
- Maxam, Allan M. and Walter Gilbert, "Sequencing End-Labeled DNA with Base-Specific Chemical Cleavages," *Methods in Enzymology*, (Lawrence Grossman, ed.) 1980, 65:499-560. (Exhibit 96)
- Maroulakou, Ioanna G. et al., "Prostate and Mammary Adenocarcinoma in Transgenic Mice Carrying a Rat C3(1) Simian Virus 40 Large Tumor Antigen Fusion Gene," *Proc. Natl. Acad. Sci. USA*, November 1994, 91:11236-40. (Exhibit 97)

- Murphy, G. et al., "Phase I Clinical Trial: T-Cell Therapy for Prostate Cancer Using Autologous Dendritic Cells Pulsed With HLA-A0201-Specific Peptides from Prostate-Specific Membrane Antigen," *The Prostate*, 1996, 29:371-80. (Exhibit 98)
- Pang, G. et al., "GM-CSF, IL-1 $\chi$ , IL-1 $\beta$ , IL-6, IL-8, IL-10, ICAM-1 and VCAM-1 Gene Expression and Cytokine Production in Human Duodenal Fibroblasts Stimulated with Lipopolysaccharide, IL-1 $\chi$  and TNF- $\chi$ ," *Clinical and Experimental Immunology*, April 1994, 96(1):437-43. (Exhibit 99)
- Panicali, Dennis and Enzo Paoletti, "Construction of Poxviruses as Cloning Vectors: Insertion of the Thymidine Kinase Gene From Herpes Simplex Virus into the DNA of Infectious Vaccinia Virus," *Proc. Natl. Acad. Sci. USA*, August 1982, 79:4927-31. (Exhibit 100)
- Pizarro, Theresa T. et al., "Induction of TNF $\alpha$  and the TNF $\beta$  Gene Expression in Rat Cardiac Transplants During Allograft Rejection," *Transplantation*, August 1993, 56(2):399-404. (Exhibit 101)
- Rosenfeld, Melissa A. et al., "Adenovirus-Mediated Transfer of a Recombinant  $\alpha$ 1-Antitrypsin Gene to the Lung Epithelium in Vivo," *Science*, April 19, 1991, 252:431-4. (Exhibit 102)
- Sarver, Nava et al., "Bovine Papilloma Virus Deoxyribonucleic Acid: A Novel Eucaryotic Cloning Vector," *Molecular and Cellular Biology*, June 1981, 1(6):486-96. (Exhibit 103)

- Schaefer-Ridder, Maria et al., "Liposomes as Gene Carriers: Efficient Transformation of Mouse L. Cells by Thymidine Kinase Gene," *Science*, January 8, 1982, 215:166-8. (Exhibit 104)
- Shimane, Miyuki et al., "Molecular Cloning and Characterization of G-CSF Induced Gene cDNA," *Biochemical and Biophysical Research Communications*, February 28, 1994, 199(1):26-32. (Exhibit 105)
- Smith, Geoffrey L. et al., "Infectious Vaccinia Virus Recombinants that Express Hepatitis B Virus Surface Antigen," *Nature*, April 1993, 302:490-5. (Exhibit 106)
- Sprecher, E. and Y. Becker, "Detection of IL-1 $\beta$ , TNF- $\alpha$  and IL-6 Gene Transcription by the Polymerase Chain Reaction in Keratinocytes, Langerhans Cells and Peritoneal Exudate Cells During Infection with Herpes Simplex Virus-1," *Archives of Virology*, 1992, 126(1-4):253-69. (Exhibit 107)
- Stavridis, J.C. et al., "Construction of Transferrin-Coated Liposomes for In Vivo Transport of Exogenous DNA to Bone Marrow Erythroblasts in Rabbits," *Experimental Cell Research*, June 1986, 164(2):568-72. (Exhibit 108)
- Tjoa, Benjamin et al., "Presentation of Prostate Tumor Antigens by Dendritic Cells Stimulates T-Cell Proliferation and Cytotoxicity," *The Prostate*, 1986, 28:65-9. (Exhibit 109)
- Ulich, Thomas R. et al., "Endotoxin-Induced Cytokine Gene Expression In Vivo III. IL-6 mRNA and Serum Protein Expression and the In Vivo Hematologic Effects of IL-6," *The Journal of Immunology*, April 1, 1991, 146(7):2316-23. (Exhibit 110)



- Wong, Gordon G. et al., "Human GM-CSF: Molecular Cloning of the Complementary DNA and Purification of the Natural and Recombinant Proteins," *Science*, May 17, 1985, 228:810-5. (Exhibit 111)
- WO 98/51805 published November 19, 1998. (Exhibit 112)
- Bzdega, Tomasz et al., "Molecular Cloning of a Peptidase Against *N*-Acetylaspartylglutamate from a Rat Hippocampal cDNA Library," *Journal of Neurochemistry*, December 1997, 69(6):2270-7. (Exhibit 113)
- Caron, Philip C. et al., "Engineered Humanized Dimeric Forms of IgG Are More Effective Antibodies," *Journal of Experimental Medicine*, October 1, 1992, 176(4):1191-5. (Exhibit 114)
- Carter, Paul et al., "Humanization of an Anti-p185<sup>HER2</sup> Antibody for Human Cancer Therapy," *Proc. Natl. Acad. Sci. USA*, May 1992, 89:4285-9. (Exhibit 115)
- Carter, Ruth E. et al., "Prostate-specific Membrane Antigen is a Hydrolase with Substrate and Pharmacologic Characteristics of a Neuropeptidase," *Proc. Natl. Acad. Sci. USA*, January 1996, 93:749-53. (Exhibit 116)
- Coloma, M. Josefina et al., "Novel Vectors for the Expression of Antibody Molecules Using Variable Regions Generated by Polymerase Chain Reaction," *Journal of Immunological Methods*, 1992, 152:89-104. (Exhibit 117)
- Graham, F. L. and A. J. Van Der Eb, "A New Technique for the Assay of Infectivity of Human Adenovirus 5 DNA," *Virology*, 1973, 52:456-67. (Exhibit 118)

- Hooijberg, Erik et al., "Eradication of Large Human B Cell Tumors in Nude Mice with Unconjugated CD20 Monoclonal Antibodies and Interleukin 2," *Cancer Research*, June 15, 1995, 55:2627-34. (Exhibit 119)
- Huang, Yi-Wu et al., "Anti-CD54 (ICAM-1) Has Antitumor Activity in SCID Mice with Human Myeloma Cells," *Cancer Research*, February 1, 1995, 55:610-6. (Exhibit 120)
- Israeli, Ron S. et al., "Expression of the Prostate-Specific Membrane Antigen," *Cancer Research*, April 1, 1994, 54(7):1807-11. (Exhibit 121)
- Jenkins, Robert B. et al., "Detection of c-myc Oncogene Amplification and Chromosomal Anomalies in Metastatic Prostatic Carcinoma by Fluorescence *in Situ* Hybridization," *Cancer Research*, February 1, 1997, 57(3):524-31. (Exhibit 122)
- Jones, Peter T. et al., "Replacing the Complementarity-Determining Regions in a Human Antibody with Those From a Mouse," *Nature*, 1986, 321(6069):522-5. (Exhibit 123)
- Larson, L. N. et al., "Mouse Monoclonal Antibodies for Experimental Immunotherapy Promotes Killing of Tumor Cells," *International Journal of Cancer*, 15 December 1988, 42(6):877-82. (Exhibit 124)
- Morton, Thomas A. and David G. Myszka, "Kinetic Analysis of Macromolecular Interactions Using Surface Plasmon Resonance Biosensors," *Methods in Enzymology*, 1998, 295:268-94. (Exhibit 125)
- Riechmann, Lutz et al., "Reshaping Human Antibodies for Therapy," *Nature*, March 1988, 332:323-7. (Exhibit 126)

- Shopes, Bob, "A Genetically Engineered Human IgG Mutant With Enhanced Cytolytic Activity," *The Journal of Immunology*, May 1992, 148:2918-22. (Exhibit 127)
- Shizuya, Hiroaki et al., "Cloning and Stable Maintenance of 300-kilobase-pair Fragments of Human DNA in *Escherichia coli* Using an F-factor-based Vector," *Proc. Natl. Acad. Sci. USA*, September 1992, 89:8794-7. (Exhibit 128)
- Sims, Martin J. et al., "A Humanized CD18 Antibody Can Block Function Without Cell Destruction," *The Journal of Immunology*, August 1993, 151(4):2296-308. (Exhibit 129)
- Slovin, S. F. et al., "Epidermal Growth Factor Receptor (EGFr) Monoclonal Antibody (MoAb) C225 and Doxorubicin (DOC) In Androgen-Independent (AI) Prostate Cancer (PC): Results of a Ib/Ila Study," *Program/Proceedings American Society of Clinical Oncology*, May 1997, 16:311a. (Exhibit 130)
- Su, Zao-Zhong et al., "Surface-epitope Masking and Expression Cloning Identifies the Human Prostate Carcinoma Tumor Antigen Gene PCTA-1 a Member of the Galectin Gene Family," *Proc. Natl. Acad. Sci. USA*, July 1996, 93:7252-7. (Exhibit 131)
- Towbin, Harry et al., "Electrophoretic Transfer of Proteins From Polyacrylamide Gels to Nitrocellulose Sheets: Procedure and Some Applications," *Proc. Natl. Acad. Sci. USA*, September 1979, 76(9):4350-4. (Exhibit 132)
- Vaughan, Tristan J. et al., "Human Antibodies by Design," *Nature Biotechnology*, June 1998, 16(6):535-9. (Exhibit 133)
- Verhoeyen, Martine et al., "Reshaping Human Antibodies: Grafting an Antilysozyme Activity," *Science*, March 1988, 239:1534-6. (Exhibit 134)

- Wolff, Edith A. et al., "Monoclonal Antibody Homodimers: Enhanced Antitumor Activity in Nude Mice," *Cancer Research*, June 1993, 53(11):2560-5. (Exhibit 135)
- Yang, Xiao-Dong et al., "Eradication of Established Tumors by a Fully Human Monoclonal Antibody to the Epidermal Growth Factor Receptor without Concomitant Chemotherapy," *Cancer Research*, March 1999, 59(6): 1236-43. (Exhibit 136)
- Cama, C., et al., "Molecular Staging of Prostate Cancer: II. A comparison of the Application of an Enhance Reverse Transcriptase Polymerase Chain Reaction Assay for Prostate Specific Antigen Versus Prostate Specific Membrane Antigen", *The Journal of Urology*, 1995, 153:1373-1378 (Exhibit 137)
- Horoszewicz, J. S., et al., "Monoclonal Antibodies to a New Antigenic Marker in Epithelial Prostatic Cells and Serum of Prostatic Cancer Patients", *Anticancer Research*, 1987, 7:927-936 (Exhibit 138)
- Israeli, R. S., et al., "Sensitive Nested Reverse Transcription Polymerase Chain Reaction Detection of Circulating Prostatic Tumor Cells: Comparison of Prostate-specific Membrane Antigen and Prostate-specific Antigen-based Assays", *Cancer Research*, 1994, 54:6306-6310 (Exhibit 139)
- Smith, M. R., et al., "Prostate-specific Antigen Messenger RNA is Expressed in Non-Prostate Cells: Implications for Detection of Micrometastases", *Cancer Research*, 1995, 55:2640-2644 (Exhibit 140)

- Sodee, D. B., et al., "Preliminary Imaging Results Using In-11 Labeled CYT-356 (Prostascint™) in the Detection of Recurrent Prostate Cancer", *Clinical Nuclear Medicine*, 1996, 21:759-767 (Exhibit 141)
- Wu, J. T., et al., "Assay for Prostate Specific Antigen (PSA): Problems and Possible Solutions", *Journal of Clinical Laboratory Analysis*, 1994, 8:51-62 (Exhibit 142)
- WO 98/51824 published November 19, 1998 (Exhibit 143)
- Colowick, et al., Methods in Enzymology 65:499-560 (1980) (Exhibit 144)
- Muller, et al., 1991 *Molec. Cell. Biol.* 11:1785-1792 (Exhibit 145)

This statement should be considered because it is submitted within three months of the filing date of the subject application according to 37 C.F.R. §1.97(b)(1). In accordance with 37 C.F.R. §1.98(d)(2), copies of Exhibits 1-145 as set forth in the enclosed Form 1449 are not provided herein as they have been previously provided to the U. S. Patent Office in the prior application to which the subject application claims priority. The subject application claims priority of U.S. Serial Nos. 09/564,329 filed May 3, 2000. Exhibits 1 through 145 have been provided to the U.S. Patent Office for the priority application.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that the

references have been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-0306.

Respectfully submitted,



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Robert E. Reiter et al.  
Serial No.: 09/934,773  
Filed: August 21, 2001  
Docket: 30435.54USD3  
Title: PSQA: PROSTATE STEM CELL ANTIGEN AND USES THEREOF

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CERTIFICATE UNDER 37 CFR 1.8

I hereby certify that this paper or fee is being deposited with the United States Postal as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on October 24, 2001.

By: 

Name: Tracy Trujillo

35 N. Arroyo Parkway, Suite 60  
Pasadena, California 91103  
October 24, 2001

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

We are transmitting herewith the attached:

- ☒ Transmittal sheet, in duplicate, containing Certificate under 37 CFR 1.8.
- ☒ Information Disclosure Statement (37 C.F.R. §1.97 (b)(1))
- ☒ Form 1449 (Information Disclosure Statement)
- ☒ Return postcard

Please charge any additional fees or credit overpayment to Deposit Account No. 50-0306. A duplicate of this sheet is enclosed.

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